

REMARKS

Reconsideration of this application is requested in view of the amendments to the claims and the remarks presented herein.

The claims in the application are claims 1 to 10 and 15 and 20, all other claims having been cancelled.

Claims 1 to 15 were rejected under 35 USC 112, second paragraph, as being indefinite. The Examiner objected to the expression “and especially mites” as being indefinite and also objected to the use of the characterized clause and objected to the expression “free from human or animal elements” as being unclear. The Examiner also objected to the expression “such as” and noted that claims 14 and 15 did not end in a period.

Applicants respectfully traverse these grounds of rejection since the amended claims are believed to properly define the invention so as to comply with 35 USC 112. The expression “and especially mites” has been deleted from the claims and the characterizing clause has been deleted as well. Periods have now been supplied for claims 14 and 15 and expression “such as” has been deleted from the claims. Therefore,

the amended claims are believed to comply with 35 USC 112 and withdrawal of this ground of rejection is requested.

With respect to the expression “free from human or animal elements” as set forth in claim 1, it is deemed that one skilled in the art would know what is meant by this terminology. The prior art media contains human scales as noted in lines 19 to 22 of page 1 or proteins from animal origin as noted in lines 28 to 30 of page 1 and these non-mite substances of human or animal origin may cause allergies and/or have an infectious potential as noted in lines 30 to 33 of page 1.

To circumvent the risks of contamination, human skin scales intended to be used for the cultivation of mites were treated to inactivate conventional viruses and bacteria or unconventional infectious agents such as prions as indicated in lines 19 to 22 of page 1 and line 34 of page 1 through line 3 of page 2. The claimed medium for cultivating mites has been developed to meet the need for a nutrient medium which minimizes the risk of the presence of infectious agents which may be found in animals or humans as indicated in lines 8 to 12 of page 2 and which is free from allergens of human or animal origin as indicated in lines 4 to 7 of page 2. The goal of Applicants’ invention is achieved by providing a medium which is free from any element of human or animal origin.

Applicants believe that one skilled in the art would readily understand that the term “human or animal elements” includes, for instance, proteins derived from an animal

or a human, infectious agents such as viruses or bacteria or unconventional infectious agents as prions that may be found in human or animals or any other elements such as human skin scales, shrimp eggs, powdered pig's liver or carbohydrates, lipids, etc. that originate from humans or animals. Therefore, it is believed that claim 1 is clear and withdrawal of these grounds of rejection is requested.

Claims 1, 4, 5 and 11 were rejected under 35 U.S.C. 102 as being anticipated by or under 35 U.S.C. 103 as being obvious over the Rodriguez et al. reference. Claims 2-3, 6-10, 12-15 and 20 stand rejected under 35 U.S.C. 103 as being obvious from Rodriguez et al. taken in view of the newly cited Singh, Yi et al and Miyamoto et al.. The Examiner states that Rodriguez et al teaches for cultivating a medium producing mites comprising amino acids in lyophilized forms referring to the abstract on pages 979 and 981. The Examiner deems that the claims are identical to the disclosed subject matter and therefore deemed to be anticipated or obvious therefrom. The secondary references are cited to show specific mites and specific salts.

Applicant respectfully traverses grounds of rejection since the cited art in no way anticipates or renders obvious applicant's invention which is drawn to a medium for culturing mites, which medium is deprived of substances of human or animal origin such as human scales or powdered pig's liver as sources of amino acids. Such sources of amino acids are conventionally used in the art as discussed in lines 19-20, 28-30 of page 1, and are liable to be contaminated with infectious agents. The Examiner's analysis of the Rodriguez et al. reference is completely incorrect.

The article reports the identification of essential and non-essential amino acids in the diet of a mite (as taught from the abstract which states “the essentiality or non-essentiality of amino acids for the species was determined”). The “Material and Methods” section teaches that the mites are first cultured on soft moist dog food having about 20% crude protein (as taught in the last paragraph of page 979). The cultured mites are then analyzed for amino acid content to provide the basis for a synthetic diet (discussed on page 981 in the first sentence of “Results and discussion”). The methods used for this amino acid analysis are described in a section entitled “Preparation of mites for analysis and scintillation counting of radioactive samples”. It is described that the mites are placed in 6 N HCl, then evaporated to dryness and the residue is resuspended in 0.1 N HCl, submitted to chromatography then lyophilized before performing cation exchange chromatography.

Rodriguez et al. do not describe a mite feeding diet containing lyophilized amino acids but rather a lyophilized sample, said sample being obtained from mites that were dissolved in acid. Furthermore, the synthetic diet that was developed by Rodriguez et al is disclosed in table 2 and comprises a mixture of amino acids but it is not taught that these amino acids are in particulate form with a particle size of less than 250 μm or that they are in lyophilized form. The Rodriguez et al diet comprises RNA which probably originates from an animal or liquids (methyl-p-hydroxybenzoate, formalin and KOH solutions) as taught in table 2. It is further taught that the diet is poured in glass vials. This means the culturing medium described by Rodriguez et al. is in liquid form which makes it impossible to have a plurality of amino acids in lyophilized form within it.

Therefore, applicant's medium is completely novel compared to the Rodriguez et al. teaching.

Rodriguez et al. would have given no incentive to one skilled in the art to provide a medium comprising a plurality of amino acids lyophilized or in particulate form with a particle size of less than 250 μm and does not address the question of the impact of the form of the amino acids on culturing yield. Contrary to the Examiner's assumption, the provision of amino acids in particulate form of particle size $< 250 \mu\text{m}$ or in lyophilized form is not an insignificant difference from the Rodriguez et al. Applicant's goal of providing a method for cultivating and producing mites that minimises the risk of the presence of infectious agents of animal or human origin as taught on lines 8-12 on page 2, is in no way subjected by Rodriguez et al.

To obtain applicant's objectives, the inventors sought to replace in the mite culture media, the conventional nutritional substances of human or animal origin such as human scales, shrimp eggs or powdered pig's liver, which substances constitute sources of amino acids for the mite diet in the prior art. Applicant's disclosure teaches that where commercially available amino acids are provided as such, without grinding and/or lyophilizing, the mites grow extremely poorly and the yields are very low (as taught in lines 11-15 on page 3).

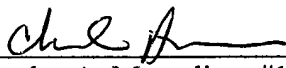
In order to establish this, applicant is filing a declaration of Dr. Thierry Batard and the results depicted in Figure 1 of the Affidavit illustrate the impact of the

replacement of human scales by a mixture of amino acids that have not been submitted to any treatment such as lyophilizing or grinding, on the culture yields. The inventors have demonstrated that these low yields may be avoided by providing the amino acids in lyophilized and/or particulate form with a particle size less than 250 μm . There is absolutely no hint in the prior art that lyophilizing or grinding crystalline amino acids to a particle size below 250 μm would make it possible to provide a medium leading to high yields of mites and allergenic activities and therefore Rodriguez et al. does not anticipate or renders obvious applicant's invention.

The combination with the secondary references does not overcome the deficiency of the Rodriguez et al reference. The Singh is merely a review of an artificial diet for mites that does not disclose or suggest replacing substances of human or animal origin with amino acids in particulate form with a particle size below 250 μm or lyophilized form. The Miyamoto et al reference discloses a culture media for mites comprising powdered animal food for laboratory mice and dry fish powder and does not suggest using amino acids in particulate form with a particle size below 250 μm or in lyophilized form, therefore, the combination in the prior art fails.

In view to the amendments to the claims and the above remarks, it is believed that the claims clearly point out applicant's patentable contribution and favorable reconsideration of the application is requested.

Respectfully submitted,
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Enclosure